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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,721	06/25/2001	James S. Huston	P 23,611-A USA	2094

7590

12/17/2004

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EXAMINER

LIETO, LOUIS D

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/888,721

Applicant(s)

HUSTON ET AL.

Examiner

Louis D Lieto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/20/04.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of applicant's response to the response 1/20/2004. Applicant's traversal of the Election/Restriction requirement is noted. Applicant's argument that the claim groups in the previous Restriction requirement were deficient is found to be persuasive. Applicant should note that the examiner of record is now Dr. Louis D. Lieto of Art Unit 1632. Upon further review and reconsideration to the arguments filed on 1/20/2004, the previous restriction requirement is vacated in light of the new restriction requirement hereto:

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention:

- (I) The invention lists the following patentably distinct species of gene delivery compounds:
- A) comprising a single chain binding polypeptide and a nucleic acid binding moiety.
 - B) comprising a single chain binding polypeptide, a nucleic acid binding moiety and a nucleic acid binding effector segment
 - C) comprising a single chain binding polypeptide, a nucleic acid binding moiety and an effector segment that facilitates endosomal escape
 - D) comprising a single chain binding polypeptide, a nucleic acid binding moiety and an effector segment that facilitates non-endosomal transport

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E) comprising a single chain binding polypeptide, a nucleic acid binding moiety and an effector segment that facilitates entry into the nucleus of a target cell.

F) comprising a single chain binding polypeptide and a lipid associating moiety.

G) comprising a single chain binding polypeptide, a lipid associating moiety and an effector segment that is capable of associating with a nucleic acid

H) comprising a single chain binding polypeptide, a lipid associating moiety and an effector segment that facilitates endosomal escape

I) comprising a single chain binding polypeptide, a lipid associating moiety and an effector segment that facilitates non-endosomal transport

J) comprising a single chain binding polypeptide, a lipid associating moiety and an effector segment that facilitates entry into the nucleus

(II) If applicant elects any of the species of A-E for prosecution on the merits, applicant must select one species from the following groups:

i.) Marker: erbB2, erbB3, erbB4, p53, p21 ras, transferring receptor,

Lewis Y antigen, carcinoembryonic antigen, epidermal growth factor, or MUC1;

ii.) Nucleic acid binding moiety: salmon protamine, subfragment of salmon protamine human histone H1, subfragment of human histone H1, human protamine, subfragment of human protamine, HMG, or polylysine;

iii.) Therapeutic gene: Lymphokine, tumor necrosis factor, intrabody, tumor suppressor genes, p53, pro-apoptotic genes, suicide genes, pro-drug

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converting genes, HSV-TK, or anti-angiogenic genes; and

iv.) conjugate: C6ML3-9 sFv'-H1, C6ML3-9 sFv'-P1 or C6ML3-9 sFv'-SP

Applicant should note that he must elect a single species as set forth in the claims. Since the relevant claims read only on conjugates in group iv) above, an election of a conjugate and a derivative will be considered non-responsive.

(III) If applicant elects any of the species of F-J for prosecution on the merits, applicant must select one species from the following groups:

- i.) Marker: erbB2, erbB3, erbB4, p53, p21 ras, transferring receptor, Lewis Y antigen, carcinoembryonic antigen, epidermal growth factor, or MUC1;
- ii). Lipid associating compound from: linear, branched, cyclic, or polycyclic.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-52 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy J Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application

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status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Dr. Louis D. Lieto
Patent Examiner
Art Unit 1632

ANNE M. WEHBE' PH.D
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